**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL NO. 1456<br><br>CIVIL ACTION NO. 01-CV-12257-PBS<br><br>Hon. Patti B. Saris |
| THIS DOCUMENT RELATES TO ALL ACTIONS | |

**DEFENDANT ASTRAZENECA PHARMACEUTICALS LP'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION IN LIMINE TO EXCLUDE EVIDENCE RELATING TO GUILTY PLEAS AND SAMPLING ACTIVITY**

Defendant AstraZeneca Pharmaceuticals LP ("AstraZeneca") respectfully submits this memorandum of law in support of its motion *in limine*, pursuant to Rules 402 and 403 of the Federal Rules of Evidence, for an Order excluding from evidence at trial documents and deposition testimony relating to or referencing the sample-related guilty pleas of AstraZeneca, TAP Pharmaceutical Products, Inc. ("TAP"), and Drs. Saad Antoun, Stanley C. Hopkins, and Robert A. Berkman. Plaintiffs' recently filed pretrial disclosures include 21 exhibits and 5 deposition transcripts relating to these pleas, (listed on Appendix A attached hereto) all of which should be excluded. Defendant AstraZeneca also moves to exclude, on the same grounds, all additional documents and testimony relating to sampling activity generally.

## BACKGROUND

On June 20, 2003, AstraZeneca pled guilty in the District of Delaware to conspiracy to violate the PDMA, 21 U.S.C. §§ 353(c), 331(t), and 333(b)(1)(B), by "causing the sale of drug

[(Zoladex)] samples" in violation of 18 U.S.C. § 371. Exhibit 1[1] (Memorandum of Plea Agreement in United States v. AstraZeneca Pharmaceuticals, LP, Criminal Action No. 03-55 (D. Del.)). Three physicians, Drs. Saad Antoun, Stanley Hopkins, and Robert Berkman, also pled guilty to violating the PDMA by seeking reimbursements for free samples of Zoladex. Exhibit 2 (Memorandum of Plea Agreement in United States v. Saad Antoun, M.D., Criminal Action No. 02-13 (D. Del.)); Exhibit 3 (Memorandum of Plea Agreement in United States v. Robert A. Berkman, M.D., Criminal Action No. 03-45 (D. Del.)); Exhibit 4 (Memorandum of Plea Agreement in United States v. Stanley C. Hopkins, M.D., Criminal Action No. 02-127 (D. Del.)). In addition, TAP Pharmaceutical Products, Inc. ("TAP"), another pharmaceutical company that is not a defendant in this trial, pled guilty to a similar charge in September 2001.

Plaintiffs' pre-trial disclosures demonstrate that the Plaintiffs intend to proffer as evidence at trial documents and testimony relating to these pleas. (See Pls.' Exhibit List; Tr. at 69 (May 23, 2006)). As this Court properly suggested during the oral argument on summary judgment motions for Classes 1 and 2, neither AstraZeneca's plea, nor the pleas of TAP or the other doctors, are relevant to the elements of Plaintiffs' claims in this litigation. (See Tr. at 68 (May 23, 2006)). Because these pleas are irrelevant, and in order to avoid wasting the Court's time or diverting attention from the issues set for trial on November 6, 2006, AstraZeneca seeks an Order excluding any documents or testimony relating thereto. In addition and for the same reasons, Defendant AstraZeneca also moves to exclude all documents and testimony relating to sampling generally.

## ARGUMENT

[1] All Exhibits referenced in support of this Memorandum are attached to the Declaration of Katherine Schmeckpeper submitted herewith.

## I. ASTRAZENECA'S PLEA AND RELATED MATERIALS ARE IRRELEVANT

AstraZeneca's plea should be excluded because it is not relevant to the claims asserted by Plaintiffs; that is, it does not make the existence of any fact of consequence to the determination of this action more or less probable. FED. R. EVID. 401; see also United States v. Smith, 940 F.2d 710, 713 (1st Cir. 1991); 2-401 Jack B. Weinstein & Margaret Berger, WEINSTEIN'S FEDERAL EVIDENCE § 401.04 (2006) ("Relevance is not inherent in any item of evidence but exists only as a relation between an item of evidence and a matter properly provable in the case."). In determining the relevance of proffered evidence, the court should "consider the relationship of the evidence sought to be admitted to the elements of the offense and to relevant defenses offered." Smith, 940 F.2d at 713. Where a party seeks to introduce evidence that does not bear a logical connection to a fact at issue, the court should exclude it under Federal Rule of Evidence 402. Id. (holding evidence properly excluded as irrelevant because Defendant's belief in the legality of his conduct was not a defense to statute prohibiting gun possession by convicted felon); Farrington v. United States, 920 F. Supp. 12, 14 (D.N.H. 1996) (excluding evidence because not relevant to issues being litigated).

### A. AstraZeneca's plea is not relevant to Plaintiffs' claims.

Plaintiffs' theory of 93A liability has been recited in numerous filings to this Court: AstraZeneca allegedly engaged in an unfair and deceptive practice by causing the publication of AWPs that "did not reflect averages of real prices in the marketplace" and "market[ing] the spreads . . . in order to protect or gain market share." (Pls.' Mot. for Partial Summ. J. at 1). In contrast, AstraZeneca's June 2003 plea has nothing to do with the AWP or Zoladex. Rather, AstraZeneca pled guilty to one count of violating the Prescription Drug Marketing Act, which

prohibits the sale, purchase, or trade of drug samples.[2] 21 U.S.C. § 353(c)(1). Plaintiffs' Complaint does not allege a claim based on the PDMA. In fact, Plaintiffs could not allege a claim under the PDMA because the PDMA does not afford a private right of action. See 21 U.S.C. § 337(a); see also Talbott v. C.R. Bard, Inc., 63 F.3d 25, 29 (1st Cir. 1995). This litigation simply has nothing to do with drug sampling or the myriad legal requirements that regulate sampling activities by pharmaceutical companies.

Furthermore, the plea bears no relation to the issues set for trial in November. In their recent filing regarding the scope of the November trial, Plaintiffs described the issues to be resolved as follows:

- Did each Defendant cause an AWP to be published?
- Did each Defendant cause an AWP to be published that did not meet the statutory definition of AWP?
- Did Defendants' conduct cause Class 2 TPPs to pay more than they should have?
- Is the practice of causing phony AWPs to be published in the context of the statutory based payment scheme unfair? Is it deceptive?
- Was Defendants' conduct willful thus triggering double or treble damages under 93A?
- The extent of Class 2 damages.

(Pls.' Mem. On Scope of November Trial at 1-2). Billing for free samples is entirely unrelated to these issues. Moreover, in the same filing, Plaintiffs strongly discouraged the Court from adding any additional issues that could muddy this "clean shot" trial. (Id. at 1). Nonetheless, despite the absence of a sampling claim here, Plaintiffs are attempting to muddy the waters by introducing evidence relating to billing for samples in the trial of their 93A AWP claims.

[2] The PDMA prohibits the sale, purchase, or trade of drug samples that could then be resold to patients and consumers. However, in recognition of the benefit conferred by the distribution of samples by pharmaceutical companies, the PDMA permits manufacturers to disseminate samples in certain circumstances. 21 U.S.C. § 353(d).

Finally, any attempt by Plaintiffs to draw a connection between sampling and their 93A AWP "inflation" claims is belied by Plaintiffs' own expert report. Plaintiffs' purported rationale for the relevance of AstraZeneca's plea is their theory that billing for free samples increases the "spread" between acquisition cost and the reimbursement amount. Although Plaintiffs' theory correctly states a mathematical proposition, there is no factual basis in the record to support its relevance to Plaintiffs' AWP "inflation" claims. Despite having access to data and documents from AstraZeneca on samples, Plaintiffs' expert—upon whom they rely to establish liability and causation on a class-wide basis—does not offer any analysis or opinion on the impact of billed samples on the average selling price or the spread between the average selling price and AWP. In fact, Dr. Hartman does not discuss free samples at all in connection with his evaluation of AstraZeneca's alleged AWP "inflation." As a result, Plaintiffs have no basis for their assertion that the limited sampling activity at issue in the plea is relevant to their ability to establish liability, causation, or damages with respect to their AWP "inflation" claims against AstraZeneca on a class-wide basis. See United States v. Ames, No. 94-30114, 1995 U.S. App. LEXIS 5428, at *2-3 (9th Cir. Mar. 18, 1995) (appellant's guilty plea to drug offense was properly excluded as irrelevant to charge of carrying a firearm in relation to a drug trafficking crime because "guilty plea on count I [sic] does not make his guilt on Count II more probable or less probable than it would be without the evidence.") (internal citation omitted).

**B. There is no connection between sampling activity in the plea and Class 2 or 3.**

Moreover, there is no connection between the Class 2 or 3 representatives and the conduct described in AstraZeneca's plea.[3] The June 20, 2003 plea is limited in both time and scope. The Information states that from 1993 to July 1996, in the District of Delaware and elsewhere, certain AstraZeneca employees provided samples to certain urologists free of charge with the intention and expectation that the physician would submit claims for payment for the samples in violation of the PDMA. Exhibit 5 (Information filed in United States of America v. AstraZeneca Pharmaceuticals, LP., Criminal Action No. 03-55 (D. Del.) ¶ 5-6, 8). Furthermore, the Information only identifies two physicians who improperly billed for samples—Dr. Saad Antoun and Dr. Stanley Hopkins—neither of whom practiced medicine in Massachusetts.[4] (Id. ¶ 10); Exhibit 6 (Information filed by U.S. Attorney in United States v. Saad Antoun, M.D., Criminal Action No. 02-13 (D. Del.) ¶ 1); Exhibit 7 (Information filed by U.S. Attorney in United States v. Stanley C. Hopkins, M.D., Criminal Action No. 02-127 (D. Del.) ¶ 1)).

In contrast, the Plaintiff classes are limited to Third-Party Payors (TPPs) and consumers who made co-payments or reimbursements based on AWP for drugs purchased in Massachusetts or whose principle place of business is in Massachusetts. There is no evidence that any of the class members reimbursed a provider for a sample or made a co-payment for a sample. Furthermore, there is no evidence that any of the patients treated by Drs. Antoun, Berkman, or

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[3] Ironically, Plaintiffs argue in their Motion in Limine to Exclude Testimony by Non-Massachusetts Third-Party Payors that conduct outside of Massachusetts is irrelevant to the determination of their claims, yet attempt to introduce evidence of limited sample billing activity completely unrelated to Massachusetts TPPs or consumers as evidence of AWP "inflation" within the Commonwealth.

[4] An additional physician, Dr. Robert Berkman, also pled guilty to similar conduct. Exhibit 8 (Transcript of the Plea Hearing in United States v. Robert A. Berkman, M.D., Criminal Action No. 03-45 (D. Del.)). Dr. Berkman also does not practice medicine in Massachusetts. (Id. at 6)

Hopkins were beneficiaries of the representative TPP Plaintiffs or that any class members were patients of these physicians. None of these doctors even practiced medicine in Massachusetts: Dr. Antoun practiced in New Jersey, Dr. Berkman in Ohio, and Dr. Hopkins in Florida.

In sum, there is no link between the limited sample billing conduct at issue in the plea and the class representatives in this action. Plaintiffs cannot be permitted to utilize the AstraZeneca plea as a proxy for evidence that does not exist. In the absence of any such evidence connecting the AstraZeneca plea to the transactions in this litigation, there is no basis to find any documents or testimony relating to the plea relevant to the issues at trial.

### C. The Pleas of Drs. Antoun, Hopkins, Berkman and TAP are not relevant.

For the same reasons, the pleas of Drs. Antoun, Berkman and Hopkins, and TAP, all of whom pled guilty to violating the PDMA, are irrelevant and should be excluded. As previously stated, Plaintiffs have not made claims under the PDMA in this litigation. Moreover, neither Dr. Antoun, Dr. Berkman nor Dr. Hopkins practiced medicine in Massachusetts and the allegations underpinning their guilty pleas do not concern pharmaceuticals purchased in Massachusetts or payments by insurers who have their principal place of business in Massachusetts. In addition, TAP is not a defendant in this trial and pled guilty to a sampling violation involving a drug that is not at issue in this litigation. In sum, there is no logical connection between the activities that formed the basis for these pleas and the claims at issue in this litigation. Accordingly, the guilty pleas of these doctors and TAP, as well as any related documents and testimony, should be excluded under Rule 402.

## II. EVIDENCE CONCERNING THESE GUILTY PLEAS AND RELATED MATERIALS WOULD CONSTITUTE A WASTE OF THE COURT'S TIME

Even if this Court were to find that the pleas are relevant—which they are not—they are so tangential to the issues in this case that they should be excluded under Federal Rule of

Evidence 403 as an unnecessary waste of the Court's time. Rule 403 permits a trial court to exclude evidence "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues . . . or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." FED. R. EVID. 403. In addition to the issue of prejudice, Rule 403 provides the Court with a valuable tool to limit and focus the evidence in complex cases and is especially appropriate when the Court has imposed time constraints for the presentation of evidence.[5] See Manual for Complex Litigation, Fourth, § 11.644. Analyzing Rule 403, the First Circuit has held that "it [is] well within the [trial] court's discretion" to exclude evidence that "though marginally relevant, [is] only tangentially related to the issue at hand." Elgabri v. Lekas, 964 F.2d 1255, 1261 (1st Cir. 1992); see also United States v. Beauchamp, 986 F.2d 1, 3-4 (1st Cir. 1993) (trial court did not err by excluding testimony that government witness had lied about his home address, since time and effort involved in presenting testimony outweighed its marginal relevance); Stathos v. Bowden, 728 F.2d 15, 19 (1st Cir. 1984) (in sex discrimination lawsuit, when issue concerned how treatment of plaintiffs compared with treatment of men holding same positions, studies of salary comparisons of employees located elsewhere were properly excluded, since they were so tangential to case as to be waste of time).

This Court should exclude the limited sampling activity evidenced in the June 2003 plea because it would only serve as an unnecessary distraction from the true issues set for resolution in the November trial. (See Tr. at 67-68 (May 23, 2006)). Otherwise, the Court will be forced to

[5] Defendant AstraZeneca notes that this evidence should be excluded from subsequent jury trials pursuant to Rule 403 because "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." FED. R. EVID. 403. Defendant AstraZeneca reserves the right to raise this argument for the Class 1 trial.

hear and review evidence concerning sampling procedures, AstraZeneca's policies with respect thereto, the lack of any connection between the pricing of Zoladex and sampling activities, the limited scope of the sampling activity at issue in the various pleas, the lack of any nexus to Massachusetts regarding any of the pleas, not to mention the lack of nexus between the pleas and Plaintiffs' experts' proffered testimony.[6] The inevitable result would be an unnecessary and time-intensive detour which bears little relevance, if any, to the Plaintiffs' claims. Moreover, the AstraZeneca Information and Dr. Berkman's plea only reference 641 total Zoladex samples that were billed. Exhibit 5 (Information in United States v. AstraZeneca Pharmaceuticals, LP, Criminal Action No. 03-55 (D. Del.) ¶¶10a, 10c (stating that AstraZeneca provided 195 free samples to Dr. Antoun and 223 free samples to Dr. Hopkins)); Exhibit 8 (Transcript of the Plea Hearing in United States v. Robert A. Berkman, M.D., Criminal Action No. 03-45 (D. Del.) at 10 (stating that Dr. Berkman received 223 free samples of Zoladex)). Accordingly, the magnitude of the conduct underlying the criminal pleas pales in comparison to the overall number of Zoladex injections sold during the class period. By way of example, the 641 samples referenced in the AstraZeneca Information and Dr. Berkman's plea (all of which were provided to patients outside of Massachusetts) constitute less than 1% of the Zoladex injections sold in Massachusetts from 1991-2002 alone. Even if this Court were to conclude that the sampling activity is marginally relevant—which it is not—it is so tangential to the issues in this case that it should be excluded.

## CONCLUSION

[6] Pending the Court's ruling on this motion, Defendant AstraZeneca has included this material in its deposition designations and Exhibit list.

For the foregoing reasons, AstraZeneca respectfully requests that this Court enter an Order excluding the evidence listed in Appendix A, including all evidence of and questions concerning AstraZeneca's plea, the guilty pleas of Dr. Antoun, Dr. Berkman, Dr. Hopkins, and TAP, and any evidence of sampling generally.

Dated: Boston, Massachusetts
October 10, 2006

Respectfully Submitted,

By: /s/ Katherine B. Schmeckpeper

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## Appendix A

Exhibits

- Plaintiffs' Exhibit 1: Memorandum of Plea Agreement in United States v. AstraZeneca Pharmaceuticals, LP, Criminal Action No. 03-55 (D. Del.)
- Plaintiffs' Exhibit 2: Information filed by the U.S. Attorney in United States v. AstraZeneca Pharmaceuticals, LP, Criminal Action No. 03-55 (D. Del.)
- Plaintiffs' Exhibit 3: Transcript of the Plea and Sentencing Hearing in United States v. AstraZeneca Pharmaceuticals, LP, Criminal Action No. 03-55 (D. Del.)
- Plaintiffs' Exhibit 4: Information filed by U.S. Attorney in United States v. Robert A. Berkman, M.D., Criminal Action No. 03-45 (D. Del.)
- Plaintiffs' Exhibit 5: Transcript of the Plea Hearing in United States v. Robert A. Berkman, M.D., Criminal Action No. 03-45 (D. Del.)
- Plaintiffs' Exhibit 6: Examples of Zoladex labels presented as Exhibits at the Ohio State Licensing Board Hearing for Robert A. Berkman, M.D.
- Plaintiffs' Exhibit 7: Information filed by U.S. Attorney in United States v. Saad Antoun, M.D., Criminal Action No. 02-13 (D. Del.)
- Plaintiffs' Exhibit 8: Memorandum of Plea Agreement in United States v. Saad Antoun, M.D., Criminal Action No. 02-13 (D. Del.)
- Plaintiffs' Exhibit 9: Memorandum of Plea Agreement in United States v. Robert A. Berkman, M.D., Criminal Action No. 03-45 (D. Del.)
- Plaintiffs' Exhibit 10: Superseding Information filed by the U.S. Attorney in United States v. Stanley C. Hopkins, M.D., Criminal Action No. 02-127 (D. Del.)
- Plaintiffs' Exhibit 11: Memorandum of Plea Agreement in United States v. Stanley C. Hopkins, M.D., Criminal Action No. 02-127 (D. Del.)
- Plaintiffs' Exhibit 12: Transcript of Sentencing Hearing in United States v. Robert A. Berkman, M.D., Criminal Action No. 03-45 (D. Del.)
- Plaintiffs' Exhibit 13: Letter from Judge Joseph J. Farnan Jr. to the State Medical Board of Ohio
- Plaintiffs' Exhibit 57: Letter to Mark J. Harberberger from William C. Lucas (10/13/95)

- Plaintiffs' Exhibit 58: Letter from Mark J. Harberberger to William C. Lucas (12/18/95)

- Plaintiffs' Exhibit 59: Letter from Mark J. Harberberger to Glenn M. Engleman (9/26/95)

- Plaintiffs' Exhibit 63: Internal Memorandum from Tom Chen to Mike Bonney re: Zoladex Sample Inventories

- Plaintiffs' Exhibit 174: Video Deposition of Dr. Robert A. Berkman

- Plaintiffs' Exhibit 913: Sentencing Memorandum of the United States in United States v. TAP Pharmaceutical Products, Inc., Criminal Action No. CR-01-10354-WGY (D. Mass. Dec. 6, 2001)

- Plaintiffs' Exhibit 914: United States v. TAP Pharmaceutical Products, Inc., No. CR-01-10354-WGY (D. Mass. Dec. 6, 2001) - Disposition

- Plaintiffs' Exhibit 919: Department of Justice Press Release "AstraZeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime: Company Agrees to Pay $355 Million to Settle Charges

Deposition Designations

- Plaintiffs' deposition designations of Robert A. Berkman, M.D.: 19:22; 20:1-3, 17-21; 25:16-22; 26:1-6; 30: 12-20; 31:16-22; 32:1-4; 36:21-22; 37:1-13, 19-22; 38:1-22; 39:1-7; 40:9-15; 44:16-22; 45:1-22; 46:1-3.

- Plaintiffs' deposition designations of Stanley C. Hopkins, M.D.: 26:11-22; 27:1-2, 5-10; 28: 4-19; 30:3-9; 39:20-22; 40:1-22; 41:1-5; 43:19-22; 44:1; 57:15-20; 59:12-22; 60:1-4, 21-22; 61:1-4.

- Plaintiffs' deposition designations of David Brennan: 70:8-20; 75:19-76:10; 86:10-13, 16-21; 95: 6-20.

- Plaintiffs' deposition designations of Mark Reisenauer: 74:13-16.

- Plaintiffs' deposition designations of Thomas Chen: 7:20-8:20.

**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered on October 10, 2006 to counsel for plaintiffs and to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, via LexisNexis File & Serve.

By: /s/ Katherine B. Schmeckpeper
Katherine B. Schmeckpeper (BBO# 663200)